

IN THE UNITED STATES DISTRICT COURT  
FOR THE MIDDLE DISTRICT OF GEORGIA  
COLUMBUS DIVISION

IN RE MENTOR CORP. OBTAPE	* MDL Docket No. 2004
	4:08-MD-2004 (CDL)
TRANSOBTURATOR SLING PRODUCTS	*
	Case No.
LIABILITY LITIGATION	* 4:14-cv-53 (Lewis)

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O R D E R

Defendant Mentor Worldwide LLC developed a suburethral sling product called ObTape Transobturator Tape, which was used to treat women with stress urinary incontinence. Plaintiff Marilyn Lewis was implanted with ObTape and asserts that she suffered injuries caused by ObTape. Mrs. Lewis brought a product liability action against Mentor, contending that ObTape had design and/or manufacturing defects that proximately caused her injuries. Mrs. Lewis also asserts that Mentor did not adequately warn her physicians about the risks associated with ObTape. Her husband Kenneth brought a loss of consortium claim. Mentor seeks summary judgment on all of Plaintiffs' claims, contending that Plaintiffs did not present enough evidence to create a genuine fact dispute on causation. As discussed below, the Court grants Mentor's summary judgment motion (ECF No. 32 in 4:14-cv-53).

#### SUMMARY JUDGMENT STANDARD

Summary judgment may be granted only "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a). In determining whether a *genuine* dispute of *material* fact exists to defeat a motion for summary judgment, the evidence is viewed in the light most favorable to the party opposing summary judgment, drawing all justifiable inferences in the opposing party's favor. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A fact is *material* if it is relevant or necessary to the outcome of the suit. *Id.* at 248. A factual dispute is *genuine* if the evidence would allow a reasonable jury to return a verdict for the nonmoving party. *Id.*

#### FACTUAL BACKGROUND

Marilyn Lewis sought treatment from Dr. Charles Seacrest for stress urinary incontinence. Dr. Secrest implanted Mrs. Lewis with ObTape on January 5, 2006. Dr. Secrest originally planned to implant Mrs. Lewis with Aris; Mentor was phasing out ObTape, and Aris was Mentor's newer sling. Secrest Dep. 9:9-18, ECF No. 32-5. Dr. Secrest preferred to use ObTape, though, and used it if it was available. *Id.* at 9:19-25. Dr. Secrest would still use ObTape if it was available. *Id.* Mrs. Lewis saw Dr. Secrest twice for follow-up visits. He never saw any sign of

infection, erosion, or exposure of the ObTape. Mrs. Lewis did not see Dr. Secrest after July 2006.

At some point, Mrs. Lewis began experiencing pain and recurrent urinary incontinence, and she saw a television commercial regarding transvaginal mesh complications. Plaintiffs filed this action on February 7, 2014, asserting claims for negligence; strict liability - design defect; strict liability - manufacturing defect; strict liability - failure to warn; strict liability - defective product; breach of express warranty; breach of implied warranty; fraudulent concealment; constructive fraud; discovery rule, tolling, and fraudulent concealment; negligent misrepresentation; negligent infliction of emotional distress; violation of consumer protection laws; gross negligence; unjust enrichment; loss of consortium; and punitive damages.

After Plaintiffs filed this action, Mrs. Lewis sought treatment from Dr. Steven Speights with complaints of recurrent urinary incontinence, dyspareunia, and a foreign body sensation in her vagina. Dr. Speights did not diagnose Mrs. Lewis with an erosion or infection, but he did remove the vaginal portion of her ObTape in 2014. Speights Dep. 29:15-30:25, ECF No. 32-7 in 4:14-cv-53. Plaintiffs contends that Dr. Speights identified ObTape as the source of her pain because he could "reproduce the

pain when [he] palpated her sling." Speights Dep. 27:2-7, ECF No. 33-7 in 4:14-cv-53.

#### DISCUSSION

Plaintiffs filed their action in this Court on February 27, 2014 under the Court's direct filing order. The parties agreed that for direct-filed cases, the "Court will apply the choice of law rules of the state where the plaintiff resides at the time of the filing of the complaint." Order Regarding Direct Filing § II(E), ECF No. 446 in 4:08-md-2004. Plaintiffs live in Mississippi, and all of Mrs. Lewis's ObTape-related treatment took place in Mississippi. The parties agree that Mississippi law applies to the Plaintiffs' claims.

Mrs. Lewis does not dispute that to establish all of her claims under Mississippi law, Mrs. Lewis must establish that she suffered injuries caused by a defect in ObTape. She may do so by showing that (1) ObTape had a defect that caused her injuries or (2) ObTape was defective because Mentor did not provide adequate warnings about ObTape's risks and the failure to warn caused her injuries. See *Chatman v. Zimmer, Inc.*, No. 514CV102DCBMTP, 2016 WL 3365456, at \*2 (S.D. Miss. June 16, 2016) ("[I]n order to survive summary judgment, a plaintiff must present expert testimony that the product is defective, and that the defect was the medical cause of the plaintiff's injuries."); *Harris v. Stryker Spine*, 39 F. Supp. 3d 846, 850 (S.D. Miss.

2014) (noting that a plaintiff has the "burden to prove that a product was defective and that such defect caused the plaintiff's injury"); *Wolf v. Stanley Works*, 757 So. 2d 316, 323 (Miss. Ct. App. 2000) (requiring, for failure to warn claim, that "the desired warning would have had [a] causative impact").

Plaintiffs claim that Mrs. Lewis suffered pain and discomfort that was caused by ObTape. To create a genuine factual dispute on general causation, Plaintiffs simply assert that they rely on the general expert witnesses that were disclosed by Plaintiffs' co-lead counsel in this multidistrict litigation proceeding. Pls.' Resp. Br. 12, ECF No. 33-1 in 4:14-cv-53. Specifically, Plaintiffs point to the Rule 26(a)(2) Amended Designation and Disclosure of General Expert Witnesses Applicable to All Cases in Mentor MDL 2004. *Id.*; accord Langston Decl. Ex. 65, Pls. Am. Designation and Disclosure of General Expert Witnesses, ECF No. 33-68 in 4:14-cv-53. This exhibit is simply a list of general expert witnesses who have been disclosed in this MDL, and it does not explain the experts' opinions or the basis for their opinions. The exhibit also does not state whether any of these general causation experts will be available to testify if this action goes to trial.

Plaintiffs did reference the expert report of Dr. Donald Ostergard in their statement of material facts—although the Court almost missed the reference because Plaintiffs gave the

wrong exhibit number for the report, failed to reference the report in their brief, and relied on the report to establish state of the art regarding pore size, not general causation. The Court reviewed Dr. Ostergard's report; Dr. Ostergard opined that ObTape's pore size can cause a "granuloma layer formation," which can result "in bridging fibrosis, prevention of normal tissue in-growth, scar plate formation, chronic inflammation, failure to incorporate, contracture and shrinkage of the mesh and surrounding tissues." Langston Decl. Ex. 28, Ostergard Report 2, ECF No. 33-29 in 4:14-cv-53. According to Dr. Ostergard, "[t]hese complications can lead to pain, erosion, infection, and disruption of pelvic muscle and nervous tissue anatomy." *Id.* at 2-3. Dr. Ostergard's report thus creates a genuine fact dispute on whether a defect in ObTape is capable of causing complications that lead to pain.

In addition to general causation, Plaintiffs must create a genuine factual dispute on specific causation: that a reasonable juror could conclude based on the evidence in the present record that a defect in ObTape caused Mrs. Lewis's injuries. Here, Plaintiffs argue that they presented sufficient evidence of specific causation because Mrs. Lewis's treating physician, Dr. Speights, identified ObTape as "the source causing Mrs. Lewis's pain and discomfort." Pl.'s Resp. Br. 12. Though Plaintiffs did point to evidence that Dr. Speights was able to reproduce

Mrs. Lewis's pain when he palpated her sling, they did not point to evidence that Dr. Speights (or anyone else) opined that a *defect* in ObTape caused Mrs. Lewis's pain.

As discussed above, Dr. Ostergard opined that ObTape's material properties can lead to several complications that cause pain. Those complications include a "granuloma layer formation," which can result "in bridging fibrosis, prevention of normal tissue in-growth, scar plate formation, chronic inflammation, failure to incorporate, contracture and shrinkage of the mesh and surrounding tissues." Ostergard Report 2. Plaintiffs did not present evidence that Mrs. Lewis had any of these complications. Plaintiffs acknowledge that Mrs. Lewis never had an extrusion, infection, or inflammation of her ObTape. And Plaintiffs did not present any evidence that Mrs. Lewis had bridging fibrosis, poor tissue ingrowth, scar plate formation, or mesh shrinkage. Without some evidence that a defect in ObTape caused Mrs. Lewis's injuries—that she suffered from a complication that her general causation expert attributes to a defect in ObTape—her product defect claims fail for lack of specific causation. Because Plaintiffs did not point to sufficient evidence to create a genuine fact dispute on specific causation, Mentor is entitled to summary judgment on all of Mrs. Lewis's claims based on Plaintiffs' theory that a defect in ObTape caused Mrs. Lewis's injuries.

Mrs. Lewis's claims based on a failure to warn likewise fail for lack of causation. Plaintiffs did not respond to Mentor's summary judgment motion on Mrs. Lewis's claims based on inadequate warnings, they did not explain what warnings and disclosures Mentor should have made, and they did not point to any evidence that different disclosures about the risks of ObTape would have affected Mrs. Lewis's treatment in any way. Mrs. Lewis's implanting physician, Dr. Secrest, testified that he would use ObTape if it was still available, and Plaintiffs did not point to any evidence that Dr. Secrest would have decided to use a different product to treat Mrs. Lewis had Mentor provided different warnings, disclosures, or representations regarding ObTape. Plaintiffs also did not point to any evidence that different warnings and disclosures would have made a difference in any other physician's treatment of Mrs. Lewis. For these reasons, Mentor is entitled to summary judgment on all of Mrs. Lewis's claims based on Mentor's alleged failure to disclose the true risks of ObTape.

In summary, Mrs. Lewis's claims all fail because she did not point to sufficient evidence on causation. Mr. Lewis's derivative loss of consortium claim likewise fails. See *J & J Timber Co. v. Broome*, 932 So. 2d 1, 6 (Miss. 2006) ("Loss of consortium is . . . derivative, and Mississippi law dictates



that if the underlying personal injury claim is disposed of, the loss of consortium claim cannot be maintained on its own.").

CONCLUSION

For the reasons set forth above, the Court grants Mentor's summary judgment motion (ECF No. 32 in 4:14-cv-53).

IT IS SO ORDERED, this 15th day of December, 2016.

s/Clay D. Land

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CLAY D. LAND

CHIEF U.S. DISTRICT COURT JUDGE

MIDDLE DISTRICT OF GEORGIA